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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

U.S. Supreme Court to Consider Just One Question in *Myriad Genetics*

The U.S. Supreme Court has agreed to review a Federal Circuit Court of Appeals ruling on the patentability of human genes and limited its grant of certiorari to the question "Are human genes patentable?" *The Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S., cert. granted November 30, 2012). The Federal Circuit's decision, affirming its earlier ruling in the wake of *Mayo Collaborative Services v. Prometheus, Inc.*, 132 S. Ct. 1289 (2012), concluded that isolated DNA molecules were patent eligible and that most of Myriad's "method claims" for comparing molecules to determine whether a patient's genes have mutations that could cause breast and ovarian cancer were not patent eligible. Further details about its August 2012 ruling appear in Issue 41 of this *Bulletin*. The American Civil Liberties Union is representing the parties that filed the petition for a writ of certiorari.

Kappos to Leave USPTO, Confirms Support for Software Patents

U.S. Patent and Trademark Office (USPTO) Director David Kappos reportedly plans to leave the position in January 2013. Kappos joined the office after serving as vice president and assistant general counsel for intellectual property at IBM. Widely lauded for progress in reducing PTO's patent backlog and efforts to implement the Leahy-Smith America Invents Act (AIA), Kappos thanked "the entire USPTO staff for their dedication and hard work." He also said, "I believe we have made great progress in reducing the patent backlog, increasing operational efficiency, and exerting leadership in IP policy domestically and internationally."

According to a news source, USPTO has reduced the backlog of unexamined patents from more than 750,000 to about 605,000, or 20 percent, even while applications increased 5 percent annually during his tenure. Senator Patrick Leahy (D-Vt.) said, "Director Kappos's leadership of the PTO has been applauded by Democrats and Republicans, and by all sectors of the business community." He also recognized the efforts Kappos had undertaken to implement patent reforms under the AIA.

Meanwhile, in an **address** to the Center for American Progress in late November, Kappos focused on software patents and responded to recent criticisms by noting that "during the so-called smartphone patent wars, innovation continues at a breakneck pace. A system like ours, in which innovation is happening faster than consumers can keep up, cannot fairly be characterized as 'broken.'" He also claimed that in 80 percent of the vast majority of cases involving software patents, the patents at issue have been found valid. While acknowledging challenges facing patent examiners making patentability determinations for software-implemented patent applications, Kappos also said that the United States should not "treat software differently than hardware when it comes to patentability."

NEW BIO BUSINESS VENTURES

Animal Breeding Companies Enter Joint Genomics Development Agreement

Cobb-Vantress Inc. and Hendrix Genetics B.V. have reportedly entered a joint three-year development agreement as a follow-up to a previous agreement under which they collaborated to achieve genomic breakthroughs. Said to be the largest collaboration in the animal breeding industry, the research and development partnership is intended to produce more productive animals that are less susceptible to disease. Headquartered in Siloam Springs, Arkansas, Cobb-Vantress is a leading supplier of broiler hen breeding stock. Netherlands-based Hendrix focuses on layer breeding, pig breeding, turkey breeding, aquaculture breeding, and poultry distribution. The companies have already discovered and developed genomic selection tools such as the SNP Chip, which is a glass slide that can evidently analyze between 60,000 and 1-million variations in DNA sequences. *See Cobb-Vantress, Hendrix Genetics Joint News Release*, November 12, 2012.

Nestlé Health Science and Chi-Med Create Joint Venture for Botanical-Based Medicines

According to a company news release, Nestlé Health Science has entered an agreement with Chi-Med to form a joint venture that will give Nestlé exclusive access to the Hong Kong drug maker's traditional Chinese medicine library, which includes more than 50,000 extracts from some 1,200 herbal plants. The new venture, Nutrition Science Partners Ltd. (NSP), will research, develop, manufacture, and market nutritional and medicinal products derived from botanical plants. Initially, NSP will develop therapies for gastrointestinal health and may expand later into metabolic disease and brain health. The transaction is subject to regulatory approval. *See Nestlé Health Science Press Release*, November 28, 2012.

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INVESTOR NEWS

Rib-X Pharmaceuticals Raises $67.5 Million to Develop Skin Infection Treatments

Connecticut-based Rib-X Pharmaceuticals has apparently closed the first tranche of a $67.5-million Series 2 preferred stock financing. The company expects a second tranche to close by the end of 2012. According to a company statement, the proceeds will be used to initiate a "Phase 3 clinical program for delafloxacin for the treatment of acute bacterial skin and skin structure infections." CEO Mark Leuchtenberger said, "Delafloxacin has consistently demonstrated its broad utility as a well-tolerated, broad spectrum antibiotic that effectively targets resistant pathogens." The antibiotic, intended to be used as a first-line antibiotic in hospitals before a specific diagnosis is available, reportedly performed successfully in Phase 2b. *See Rib-X Pharmaceuticals Press Release*, November 29, 2012.

Intarcia Therapeutics Secures $210 Million to Advance Type 2 Diabetes Therapy

According to a news source, biotechnology company Intarcia Therapeutics, Inc. has completed two financings with proceeds of $210 million, said to be the largest sum raised by a private company in this sector in 25 years. The funds will reportedly be used to initiate a global Phase 3 program for its lead candidate ITCA 650® for the treatment of type 2 diabetes. The California-based company describes ITCA 650® as a "continuous subcutaneous delivery of exenatide" that, "if approved, would be the first and only type 2 diabetes once-yearly, injection-free GLP-1 therapy."

The product involves a miniature osmotic pump inserted subcutaneously and the company's proprietary formulation technology that "maintains stability of therapeutic proteins and peptides at human body temperatures for long extended periods of time." The Phase 2 program evidently showed "significant and sustained reductions in HbA1c and body weight over 48 weeks of treatment with a marked reduction in the GI adverse events typically associated with the self-injection products in this class." *See Intarcia Therapeutics, Inc. Press Release*, November 15, 2012.

Biotech Raises $37.5 Million to Fund Retinal Disease Therapy Products

Applied Genetic Technologies Corp. has reportedly raised $37.5 million in a Series B financing round. According to a company statement, "Alta Partners and S.R. One, Limited led the financing, with new investor Osage University Partners joining existing investors InterWest, Intersouth Partners and MedImmune Ventures in the round." The Florida-based clinical-stage biotech will use the funds to continue developing its Phase 2 program for Alpha-1 Antitrypsin Deficiency, a condition that can lead to the development of emphysema and chronic obstructive pulmonary disease-like symptoms at an early age, and to

initiate development of potential treatments for rare genetic visual impairments, such as Achromatopsia (ACHM) and X-Linked Rentinoschisis (XLRS).

Most ACHM patients are legally blind; they lack color discrimination and experience extreme light sensitivity. Some 22,000 patients in the United States and Europe have this disease. XLRS is the leading cause of juvenile macular degeneration in males and affects some 35,000 patients in the United States and Europe. Applied Genetic Technologies focuses on novel therapeutics for patients with unmet medical needs and bases its research and development activity on its proprietary, non-pathogenic adeno-associated virus delivery system. Another candidate in the company's pipeline is intended to treat Leber's congenital amaurosis, a form of childhood blindness. *See Business Wire*, November 19, 2012.

Netherlands Biopharmaceutical Receives €10 Million in Equity Financing

Kiadis Pharma B.V., which develops biotech treatments for blood cancers, has reportedly secured €10 million in an equity financing round. The Amsterdam-based clinical-stage biopharmaceutical company will use the funds to "perform a confirmatory multi-center Phase II proof-of-concept study with its lead product ATIR™, and to prepare a pivotal Phase II/III study." Kiadis characterizes ATIR™ as "a cell-based medicinal product candidate enabling stem cell transplantations from mismatched (haploidentical) family donors to patients suffering from blood cancer." The product apparently enhances early immune reconstitution without causing graft-versus-host-disease.

Kiadis CEO Manfred Ruediger said, "We are delighted with the enthusiastic support from existing and new investors, which attests to the exciting clinical data generated for ATIR™ in close cooperation with our clinical investigators in North America and Europe." *See Kiadis Pharma News Release*, November 20, 2012.

NanoBio Corp. Closes $11-Million Series C Financing to Develop Anti-Infective Treatments

NanoBio Corp. has reportedly closed an $11-million Series C financing round that included the full participation of its existing investors. The Ann Arbor, Michigan-based biopharmaceutical company develops and commercializes dermatological products, anti-infective treatments and intranasal and intramuscular vaccines derived from its NanoStat™ technology platform. It will apparently use the financing proceeds to advance its "development programs for herpes labialis (cold sores), cystic fibrosis and nanoemulsion-based vaccines for respiratory syncytial virus (RSV) and genital herpes (HSV2)."

CEO David Peralta said, "Our topical therapeutic programs continue to show tremendous promise to enable new products that can effectively treat drug-resistant pathogens and avoid the concerning safety risks associated with oral

therapies. In addition, recent studies with our vaccine technology highlight key advantages for developing new vaccines for widespread respiratory and sexually transmitted diseases. Our unique ability to elicit both systemic immunity and mucosal immunity at the sites where these viruses enter the body could prove essential in the development of vaccines for RSV, HSV2 and other diseases." *See NanoBio Corp. Press Release*, November 29, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

USPTO Announces Roundtable on Real-Party-in-Interest Information

The U.S. Patent and Trademark Office (USPTO) will conduct a **roundtable** in January 2013 to obtain public input on whether it should promulgate regulations "that would require greater public transparency concerning the ownership of patent applications and patents by requiring the provision of real-party-in-interest information during patent prosecutions and at certain times post-issuance." Those wishing to participate in the January 11 round-table in Alexandria, Virginia, must submit a request no later than December 21, 2012. Written comments must be submitted by January 25, 2013.

According to USPTO, "Markets operate most efficiently when buyers and sellers can find one another. Yet in our current system, fragmented ownership in the patent rights covering complex products leads to potential buyers facing difficulty finding sellers, and to potential innovators not understanding the nature of the marketplace they are considering entering."

In USPTO's view, the benefits of more complete patent ownership information include (i) better public understanding "of what patent rights being issued by the United States are being held and maintained by various entities"; (ii) more complete information for financial markets "about the valuable assets being generated and held by companies"; (iii) better allocation of research and development resources by inventors and manufacturers on the basis of an improved understanding of the competitive environment, as well as the ability to "more efficiently obtain licenses and accurately value patent portfolios and patent estates that they may seek to acquire"; and (v) facilitated USPTO patent examination. *See Federal Register*, November 26, 2012.

FDLI's *Food and Drug Policy Forum* Focuses on Naming Biosimilars

The Alliance for Safe Biologic Medicines has called for the adoption of a unique U.S. Adopted Name (USAN) for biologic and biosimilar therapeutics as "a foundational element of the safety framework" for the biosimilar approval pathway that the Food and Drug Administration (FDA) is required to establish under the Affordable Care Act.

In his November 28, 2012, article published in the Food and Drug Law Institute's (FDLI's) biweekly *Food and Drug Policy Forum,* Alliance Chair Richard Dolinar claims that patient safety and the need for traceability require USANs for biosimilars. He suggests that the "non-proprietary name of a reference product and product[s] biosimilar to it should have a common, shared root but have distinct and differentiating suffixes" and that "[p]roducts designated interchangeable should have a distinct name from the reference product for which they are considered interchangeable to facilitate accurate attribution of adverse events."

Dolinar explains how biologic identification using National Drug Codes, as called for by some stakeholders, would not be practical and explores the European experience with biosimilar naming, which has apparently resulted in difficulties tracing biologics when adverse events occur. He also recommends that the United States Pharmacopeia (USP) "work with FDA to adapt the product monograph system to accommodate the unique attributes of structurally related but distinct biologic medicines." The Alliance is apparently concerned that USP has indicated in its FDA submissions "that the issuance of a monograph should dictate the nomenclature for a biologic medicine." Dolinar opines that the monograph system could be adapted "to accommodate prefixes or suffixes while still permitting the enforcement of common standards."

Massachusetts Adopts Rules on Manufacturers' Gifts to Health-Care Practitioners

The Massachusetts Department of Public Health has approved final **amendments** to a rule governing pharmaceutical and medical device manufacturer conduct. The rule prohibits certain gifts, such as tickets to shows, golf outings and cash, and explains under what circumstances meals can be provided and payments can be made for bona fide services, technical training, prescription drugs for use by patients, and charitable contributions, among others. The changes to the rules include reporting requirements. The department's goals in making the changes included maintaining a high level of public information available and aligning state law with standards set by the legislature and two industry codes of conduct.

LITIGATION

Federal Circuit Applies Patent Issuance Date to Laches Claim in Inventorship Correction Suit

The Federal Circuit Court of Appeals has ruled that a claim for correction of inventorship under 35 U.S.C. § 256 accrues when the patent issues and not when the allegedly omitted inventors purportedly knew or should have known that they were not named inventors on the patent application. ***Hor v. Chu*, No. 2011-1540 (Fed. Cir., decided November 14, 2012)**. So ruling, the

court reversed the district court's dismissal of the action on grounds of laches and equitable estoppel.

According to the Federal Circuit, the statute is clear that the laches clock does not begin to run, at the earliest, until the patent issues. The court also found that the lower court erred in granting summary judgment on the affirmative defense of equitable estoppel because the court raised the issue *sua sponte*. The defense should have been, but was not, pleaded by the patent holder.

The patents at issue involved research related to high temperature superconducting compositions; the patent holder was a professor of physics at the University of Houston, and the allegedly omitted inventors were a research assistant and independent materials scientist who was part of the professor's research group. A concurring appeals court judge agreed with the majority's statutory analysis, but, in the interest of more prompt resolution of inventorship issues, suggested that Congress amend the law to require earlier claim filing.

Prior Trademark Litigation No Bar to Patent Infringement Claim

A divided Federal Circuit Court of Appeals panel has ruled that a patent infringement claim involving an undercarriage system for conveyor belts is not barred by claim preclusion even though the parties had previously litigated a trademark infringement action arising from advertisements for a product based on the patented technology. ***Superior Indus., LLC v. Thor Global Enters. Ltd.*, No. 2011-1549 (Fed. Cir., decided November 27, 2012)**. The panel majority concluded that because the advertisements did not include pricing information, they could not be construed as an "offer" that an offeree "could make into a binding contract by simple acceptance." Thus, the defendant's "advertising at issue in the 2009 Trademark Action did not constitute an 'offer of sale' for purposes of patent infringement because it contains no price terms."

The dissenting judge disagreed, finding that the plaintiff's patent infringement action was based "on the same nucleus of operative facts as its earlier trademark infringement suit . . . [because] both relate to [the defendant's] fully-braced undercarriages for portable conveyor systems, which were advertised and allegedly offered for sale in 2007." According to this jurist, "Notwithstanding the fact that the 2007 advertising materials did not contain pricing information, such materials were clearly sufficient to put [the plaintiff] on notice that it had a potential patent infringement claim." The dissenting judge added, "[the defendant] should not be forced to endure a second round of litigation simply because [the plaintiff], for its own strategic reasons, chose to delay assertion of its patent claims until after its trademark suit was fully resolved."

AIPLA *Amicus* Brief Urges SCOTUS to Keep Patent Malpractice Suits in State Court

In an **amicus brief**, the American Intellectual Property Law Association (AIPLA) urges the U.S. Supreme Court to scale back the Federal Circuit Court of Appeals' view of jurisdiction over state-law claims that involve patent-law issues. *Gunn v. Minton*, No. 11-1118 (U.S., AIPLA *amicus* brief filed, November 26, 2012). Additional information about the U.S. Supreme Court's decision to review a Texas Supreme Court ruling dismissing a legal malpractice action arising out of patent-infringement litigation appears in Issue **44** of this *Bulletin*.

AIPLA catalogs the types of state-law claims involving patent-law issues over which the Federal Circuit has exercised jurisdiction since the U.S. Supreme Court decided *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988); the Federal Circuit apparently interpreted that opinion "as providing a 'lenient standard' for jurisdiction." According to AIPLA, "Unless this Court overrules the Federal Circuit's post-*Christianson* precedent, that precedent will continue to cause the district courts to exercise jurisdiction over various state-law claims merely because those claims raise a patent-law issue. This diminishes the right of litigants to select a forum based on the traditional well-pleaded complaint rule."

NEWS BYTES

Heads of the U.S. Patent and Trademark Office (USPTO), European Patent Office and Japan Patent Office—collectively known as the Trilateral Offices—**confirm** their commitment to eliminating unnecessary duplication of work, enhancing patent examination and quality, and working to ensure that stable patent rights can be granted smoothly and easily worldwide. USPTO will host the 31st Annual Trilateral Conference in fall 2013.

The U.S. Patent and Trademark Office (USPTO) **chooses** the Terminal Annex Federal Building as the site for its Dallas-Fort Worth regional satellite office, where small businesses and entrepreneurs can navigate the patent process, meet with examiners and access USPTO's comprehensive search databases. Modeled after USPTO's first satellite office in Detroit, the new office is on pace to have more than 100 patent examiners and 20 administrative judges on board by the end of its first year of operation.

The IP5—a coalition of the world's five largest patent offices—**announces** the upcoming release of the "IP5 Statistics Report 2011 Edition." The report aims to facilitate an understanding of operations and patent procedures among the offices, provide a means for gauging inventive activity and technology flow, and compare procedures. The IP5, which handles about 80 percent of the world's patent applications, includes the U.S. Patent and Trademark Office, European Patent Office, Japan Patent Office, Korean Intellectual Property

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Office, and State Intellectual Property Office of the People's Republic of China.

The Food and Drug Administration (FDA) issues draft **guidance** titled "Guidance for Industry: Preclinical Assessment of Investigational Cellular and Gene Therapy Products" to provide recommendations on the substance and scope of preclinical information needed to support clinical trials for investigational products regulated by the Center for Biologics Research and Evaluation Office of Cellular, Tissue, and Gene Therapies. According to FDA, "The product areas covered by this guidance are cellular therapy, gene therapy, therapeutic vaccination, and xenotransplantation." The guidance clarifies current expectations for these product areas concerning the preclinical information that supports investigational new drug and biologics license applications.

The Food and Drug Administration (FDA) **amends** its July 10, 2012, proposed rule to establish a unique device identification system as required by recent amendments to the Federal Food, Drug, and Cosmetic Act. FDA would change some of the proposed effective dates for requirements applicable to implantable, lifesaving (life-supporting), and life-sustaining devices, so that the requirements applicable to these devices will be effective no later than two years from the rule's finalization. Comments are requested by December 19, 2012.

The Food and Drug Administration (FDA) **considers** an implementation strategy and policy for the custom device exemption criteria in the Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Safety and Innovation Act. FDA seeks information on appropriate uses of the custom device exemption. Comments are requested by January 18, 2013.

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